Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-103. (Cancelled)

104. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation, wherein said at least one stabilizer comprises a ligand; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

105. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer , wherein said at least one stabilizer comprises a ligand; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said stabilizer and the rate of irradiation are together effective to protect said biological material from said radiation.

106. (New) The method according to claims 104 or 105, wherein said biological material is mammalian.

107. (New) The method according to claims 104 or 105, wherein said biological material is human.

108. (New) The method according to claims 104 or 105, wherein said biological material is transgenic or recombinant.

109. (New) The method according to claims 104 or 105, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said radiation;

(b) reducing the temperature of said biological material to a level effective to protect said biological material from said radiation;

(c) reducing the oxygen content of said biological material to a level effective to protect said biological material from said radiation;

(d) adjusting the pH of said biological material to a level effective to protect said biological material from said radiation; and

(e) adding to said biological material at least one non-aqueous solvent in an amount effective to protect said biological material from said radiation

110. (New) The method according to claims 104 or 105, wherein said ligand is heparin.

111. (New) The method according to claims 104 or 105, wherein said radiation is gamma radiation.

112. (New) The method according to claims 104 or 105, wherein said irradiating is conducted at ambient temperature.

113. (New) The method according to claims 104 or 105, wherein said irradiating is conducted at a temperature below ambient temperature.

114. (New) The method according to claims 104 or 105, wherein said irradiating is conducted below the freezing point of said biological material.

115. (New) The method according to claims 104 or 105, wherein said irradiating is conducted below the eutectic point of said biological material.

116. (New) The method according to claims 104 or 105, wherein said irradiating is conducted at a temperature above ambient temperature.

117. (New) The method according to claims 104 or 105, wherein said biological material is selected from the group consisting of dextrose, urokinase, thrombin, trypsin, purified protein fraction, blood, blood cells, alpha 1 proteinase inhibitor, digestive enzymes, blood proteins and tissue.

118. (New) The method according to claims 104 or 105, wherein said biological material is plasma or serum.

119. (New) The method according to claim 117, wherein said tissue is selected from the group consisting of ligaments, tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

120. (New) The method according to claims 104 or 105, wherein said biological material is selected from the group consisting of grafts, joints, femurs, femoral heads, heart valves, ligaments, hearts, livers, lungs, kidneys, intestines, pancreas, limbs, digits and demineralized bone matrix.

121. (New) A composition comprising at least one biological material and at least one stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation, wherein said at least one biological material is glassy or vitrified.

122. (New) A composition comprising at least one biological material, wherein the residual solvent content of said biological material is at a level effective to preserve said biological material for its intended use following sterilization with radiation, and wherein said at least one biological material is glassy or vitrified.

123. (New) The composition of claim 122, wherein said residual solvent content is less than 15%.

124. (New) The composition of claim 122, wherein said residual solvent content is less than 10%.

125. (New) The composition of claim 122, wherein said residual solvent content is less than 5%.

126. (New) The composition of claim 122, wherein said residual solvent content is less than 2%.

127. (New) The composition of claim 122, wherein said residual solvent content is less than 1%.

128. (New) The composition of claim 122, wherein said residual solvent content is less than 0.5%.

129. (New) The composition of claim 122, wherein said residual solvent content is less than 0.08%.

130. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 0.5%.

131. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 1%.

132. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 5%.

133. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 10%.

134. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 15%.

135. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 20%.

136. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 25%.

137. (New) The composition of claims 121 or 122, wherein the concentration of said biological material in said solvent is at least 50%.

138. (New) The composition of claim 121, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; trehalose; mannitol; DMSO; and mixtures of two or more thereof.

139. (New) A method for prophylaxis or treatment of a condition or disease in a mammal comprising administering to a mammal in need thereof an effective amount of a composition according to claims 121 or 122.

140. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation, wherein said at least one stabilizer comprises a dipeptide stabilizer; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

141. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer, wherein said at least one stabilizer comprises a dipeptide stabilizer; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said biological material from said radiation.

142. (New) A method according to claims 140 or 141, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said radiation;

(b) reducing the temperature of said biological material to a level effective to protect said biological material from said radiation;

(c) reducing the oxygen content of said biological material to a level effective to protect said biological material from said radiation;

(d) adjusting the pH of said biological material to a level effective to protect said biological material from said radiation; and

(e) adding to said biological material at least one non-aqueous solvent in an amount effective to protect said biological material from said radiation.

143. (New) The method according to claims 140 or 141, wherein said dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

144. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation, wherein said irradiating is conducted below the glass transition point of said biological material.

145. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation;

(b) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said radiation;

(c) reducing the temperature of said biological material to a level effective to protect said biological material from said radiation;

(d) reducing the oxygen content of said biological material to a level effective to protect said biological material from said radiation;

(e) adjusting the pH of said biological material to a level effective to protect said biological material from said radiation; and

(f) adding to said biological material at least one non-aqueous solvent in an amount effective to protect said biological material from said radiation;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said irradiating is conducted below the glass transition point of said biological material.

146. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said biological material from said radiation, and said irradiating is conducted below the glass transition point of said biological material.

147. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least two stabilizing processes are together effective to protect said biological material from said radiation, said at least two stabilizing processes may be performed in any order, and said irradiating is conducted below the glass transition point of said biological material.

148. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation, wherein the recovery of the desired activity

of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

149. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation;

(b) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said radiation;

(c) reducing the temperature of said biological material to a level effective to protect said biological material from said radiation;

(d) reducing the oxygen content of said biological material to a level effective to protect said biological material from said radiation;

(e) adjusting the pH of said biological material to a level effective to protect said biological material from said radiation; and

(f) adding to said biological material at least one non-aqueous solvent in an amount effective to protect said biological material from said radiation;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, and wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

150. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said biological material from said radiation, and wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

151. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) applying to said biological material at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;

(b) reducing the residual solvent content of said biological material;

(c) reducing the temperature of said biological material;

(d) reducing the oxygen content of said biological material;

(e) adjusting the pH of said biological material; and

(f) adding to said biological material at least one non-aqueous solvent;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least two stabilizing processes

are together effective to protect said biological material from said radiation and further wherein said at least two stabilizing processes may be performed in any order, and wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

152. (New) The method according to any one of claims 144-147, wherein said biological material is mammalian.

153. (New) The method according to any one of claims 144-147, wherein said biological material is human.

154. (New) The method according to any one of claims 144-147, wherein said biological material is transgenic or recombinant.

155. (New) The method according to any one of claims 145-147, wherein said at least one stabilizer is selected from the group consisting of mannitol, trehalose, DMSO and combinations thereof.

156. (New) The method according to any one of claims 145-147, wherein said at least one stabilizer comprises mannitol.

157. (New) The method according to any one of claims 145-147, wherein said at least one stabilizer comprises trehalose.

158. (New) The method according to any one of claims 145-147, wherein said at least one stabilizer comprises DMSO.

159. (New) The method according to any one of claims 145-147, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; trehalose; mannitol; DMSO; and mixtures of two or more thereof.

160. (New) The method according to claim 159, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic; acid and mixtures of

uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

161. (New) The method according to any one of claims 144-147, wherein said radiation is gamma radiation.

162. (New) The method according to any one of claims 148-151, wherein said irradiating is conducted at ambient temperature.

163. (New) The method according to any one of claims 148-151, wherein said irradiating is conducted at a temperature below ambient temperature.

164. (New) The method according to any one of claims 148-151, wherein said irradiating is conducted below the freezing point of said biological material.

165. (New) The method according to any one of claims 148-151, wherein said irradiating is conducted below the eutectic point of said biological material.

166. (New) The method according to any one of claims 148-151, wherein said irradiating is conducted at a temperature above ambient temperature.

167. (New) The method according to any one of claims 144-147, wherein said biological material is selected from the group consisting of dextrose, urokinase, thrombin, trypsin, purified protein fraction, blood, blood cells, alpha 1 proteinase inhibitor, digestive enzymes, blood proteins and tissue.

168. (New) The method according to any one of claims 144-147, wherein said biological material is plasma or serum.

169. (New) The method according to any one of claims 144-147, wherein said biological material is selected from the group consisting of ligaments, tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

170. (New) The method according to claim 167, wherein said tissue is selected from the group consisting of grafts, joints, femurs, femoral heads, heart valves, ligaments, hearts, livers, lungs, kidneys, intestines, pancreas, limbs, digits and demineralized bone matrix.

171. (New) The method according to claim 167, wherein said tissue is selected from the group consisting of tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

172. (New) The method according to any one of claims 144-147, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

173. (New) The method according to any one of claims 144-147, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least 100% of the pre-irradiation value.

174. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation, wherein said at least one stabilizer comprises mixtures of two or more stabilizers selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-

tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

175. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said radiation, wherein said at least one stabilizer comprises mixtures of two or more stabilizers selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester

thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid;

and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material, wherein said at least one stabilizer and the rate of irradiation are together effective to protect said biological material from said radiation.

176. (New) The method according to claims 174 or 175, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) reducing the residual solvent content of said biological material;

(b) reducing the temperature of said biological material;

(c) reducing the oxygen content of said biological material;

(d) adjusting the pH of said biological material; and

(e) adding to said biological material at least one non-aqueous solvent, wherein said at least one stabilizer, said at least one stabilizing process are together effective to protect said biological material from said radiation.

177. (New) A composition comprising at least one biological material and at least one stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation, wherein said at least one stabilizer comprises:

mixtures of two or more stabilizers selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic acid

and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

178. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation, wherein said effective rate is not constant and comprises a rate of between about 0.1kGy/hr to 3.0kGy/hr for at least a portion of said period of time and a rate of at least 6.0kGy/hr for at least another portion of said period of time.

179. (New) The method according to claim 178, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) adding to said biological material at least one stabilizer;
(b) reducing the residual solvent content of said biological material;
(c) reducing the temperature of said biological material;
(d) reducing the oxygen content of said biological material;
(e) adjusting the pH of said biological material; and
(f) adding to said biological material at least one non-aqueous solvent;

wherein said at least one stabilizing process and said rate of irradiation are together effective to protect said biological material from said radiation.

180. (New) The method according to claims 178 or 179, wherein said biological material is mammalian.

181. (New) The method according to claims 178 or 179, wherein said biological material is human.

182. (New) The method according to claims 178 or 179, wherein said biological material is transgenic or recombinant.

183. (New) The method according to claims 178 or 179, wherein said at least one stabilizer is selected from the group consisting of mannitol, trehalose, DMSO, and combinations thereof.

184. (New) The method according to claims 178 or 179, wherein said at least one stabilizer comprises mannitol.

185. (New) The method according to claims 178 or 179, wherein said at least one stabilizer comprises trehalose.

186. (New) The method according to claims 178 or 179, wherein said at least one stabilizer comprises DMSO.

187. (New) The method according to claims 178 or 179, comprising applying to said biological material at least two stabilizing processes, wherein said at least two stabilizing processes and said rate of irradiation are together effective to protect said biological material from said radiation and further wherein said at least two stabilizing processes may be preformed in any order.

188. (New) The method according to claims 178 or 179, wherein said effective dose rate comprises a rate between 0.25 kGy/hr to 2.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

189. (New) The method according to claims 178 or 179, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.5 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

190. (New) The method according to claims 178 or 179, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

191. (New) The method according to claims 178 or 179, wherein said effective rate further comprises a rate of least 18.0 kGy/hour for at least another portion of said period of time.

192. (New) The method according to claims 178 or 179, wherein said effective rate further comprises a rate of least 30.0 kGy/hour for at least another portion of said period of time.

193. (New) The method according to claims 178 or 179, wherein said effective rate further comprises a rate of least 45 kGy/hour for at least another portion of said period of time.

194. (New) The method according to claims 178 or 179, wherein said biological material is maintained in a low oxygen atmosphere.

195. (New) The method according to claim 178, wherein said biological material is maintained in an atmosphere comprising at least one noble gas or nitrogen.

196. (New) The method according to claim 195, wherein said noble gas is argon.

197. (New) The method according to claims 178 or 179, wherein said biological material is maintained in a vacuum.

198. (New) The method according to claim 179, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying and vitrification.

199. (New) The method according to claim 179, wherein said residual solvent content is less than about 15%.

200. (New) The method according to claim 179, wherein said residual solvent content is less than about 10%.

201. (New) The method according to claim 179, wherein said residual solvent content is less than about 3%.

202. (New) The method according to claim 179, wherein said residual solvent content is less than about 2%.

203. (New) The method according to claim 179, wherein said residual solvent content is less than about 1%.

204. (New) The method according to claim 179, wherein said residual solvent content is less than about 0.5%.

205. (New) The method according to claim 179, wherein said residual solvent content is less than about 0.08%.

206. (New) The method according to claims 178 or 179, wherein at least one sensitizer is added to said biological material prior to irradiating.

207. (New) The method according to claims 178 or 179, wherein said biological material contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, parasites and prions or similar agents responsible, alone or in combination, for TSEs.

208. (New) The method according to claim 179, wherein said at least one stabilizer is an antioxidant.

209. (New) The method according to claim 179, wherein said at least one stabilizer is a free radical scavenger.

210. (New) The method according to claim 179, wherein said at least one stabilizer is a combination stabilizer.

211. (New) The method according to claim 179, wherein said at least one stabilizer is a ligand.

212. (New) The method according to claim 211, wherein said ligand is heparin.

213. (New) The method according to claim 179, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

214. (New) The method according to claim 179, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; vitamin E or a derivative thereof; albumin; sucrose; glycylglycine; L-carnosine; cysteine; silymarin; diosmin; hydroquinonesulfonic acid; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; ethanol; acetone; rutin; epicatechin; biacalein; purpurogallin; trehalose, mannitol, DMSO; and mixtures of two or more thereof.

215. (New) The method according to claim 214, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ethanol and acetone; mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and albumin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, albumin and sucrose; mixtures of ascorbic acid, or a salt or ester thereof, and glycylglycine; mixtures of ascorbic acid, or a salt or ester thereof, glycylglycine and albumin; mixtures of ascorbic acid, or a salt or ester thereof and L-carnosine; mixtures of ascorbic acid, or a salt or ester thereof and cysteine; mixtures of ascorbic acid, or a salt or ester thereof and N-acetyl cysteine; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and silymarin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and diosmin; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and lipoic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and hydroquinonesulfonic; acid and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

216. (New) The method according to claim 179, wherein said at least one stabilizer is a dipeptide stabilizer.

217. (New) The method according to claim 216, wherein said dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

218. (New) The method according to claims 178 or 179, wherein said radiation is corpuscular radiation, electromagnetic radiation, or a mixture thereof.

219. (New) The method according to claim 218, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

220. (New) The method according to claims 178 or 179, wherein said radiation is gamma radiation.

221. (New) The method according to claims 178 or 179, wherein said radiation is E-beam radiation.

222. (New) The method according to claims 178 or 179, wherein said radiation is visible light.

223. (New) The method according to claims 178 or 179, wherein said radiation is ultraviolet light.

224. (New) The method according to claims 178 or 179, wherein said radiation is x-ray radiation.

225. (New) The method according to claims 178 or 179, wherein said radiation is polychromatic visible light.

226. (New) The method according to claims 178 or 179, wherein said radiation is infrared.

227. (New) The method according to claims 178 or 179, wherein said radiation is a

combination of one or more wavelengths of visible and ultraviolet light.

228. (New) The method according to claims 178 or 179, wherein said irradiation is conducted at ambient temperature.

229. (New) The method according to claims 178 or 179, wherein said irradiation is conducted at a temperature below ambient temperature.

230. (New) The method according to claims 178 or 179, wherein said irradiation is conducted below the freezing point of said biological material.

231. (New) The method according to claims 178 or 179, wherein said irradiation is conducted below the eutectic point of said biological material.

232. (New) The method according to claims 178 or 179, wherein said irradiation is conducted at a temperature above ambient temperature.

233. (New) The method according to claim 179, wherein said non-aqueous solvent is selected from the group consisting of glycerol, DMSO, ethanol, acetone and PPG, and mixtures thereof.

234. (New) The method according to claim 233, wherein said PPG is PPG 400, PPG 1200 or PPG 2000.

235. (New) The method according to claim 179, wherein said residual solvent content is about 0%.

236. (New) The method according to claim 179, wherein said residual solvent content is about 1%.

237. (New) The method according to claim 179, wherein said residual solvent content is about 2.4%.

238. (New) The method according to claim 179, wherein said residual solvent content is about 4.8%.

239. (New) The method according to claim 179, wherein said residual solvent content is about 7%.

240. (New) The method according to claim 179, wherein said residual solvent content is about 9%.

241. (New) The method according to claim 179, wherein said residual solvent content is about 10%.

242. (New) The method according to claim 179, wherein said residual solvent content is about 20%.

243. (New) The method according to claim 179, wherein said residual solvent content is about 33%.

244. (New) The method according to claim 179, wherein said residual solvent content is less than about 33%.

245. (New) The method according to claims 178 or 179, wherein said biological material is selected from the group consisting of dextrose, urokinase, thrombin, trypsin, purified protein

fraction, blood, blood cells, alpha 1 proteinase inhibitor, digestive enzymes, blood proteins and tissue.

246. (New) The method according to claims 178 or 179, wherein said biological material is plasma or serum.

247. (New) The method according to claim 245, wherein said tissue is selected from the group consisting of ligaments, tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

248. (New) The method according to claims 178 or 179, wherein said biological material is selected from the group consisting of grafts, joints, femurs, femoral heads, heart valves, ligaments, hearts, livers, lungs, kidneys, intestines, pancreas, limbs, digits and demineralized bone matrix.

249. (New) The method according to claim 179, wherein said residual solvent is an aqueous solvent.

250. (New) The method according to claim 179, wherein said biological material is suspended in said solvent.

251. (New) The method according to claim 179, wherein said biological material is dissolved in said solvent.

252. (New) The method according to claim 179, wherein said irradiation is conducted below the glass transition point of said biological material.

253. (New) The method according to claim 245, wherein said digestive enzymes are selected

from the group consisting of galactosidases and sulfatases.

254. (New) The method according to claim 245, wherein said blood proteins are selected from the group consisting of albumin, Factor VIII, Factor VII, Factor IV, fibrinogen, monoclonal immunoglobulins and polyclonal immunoglobulins.

255. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is greater than 100% of the pre-irradiation value.

256. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 100% of the pre-irradiation value.

257. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 90% of the pre-irradiation value.

258. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 80% of the pre-irradiation value.

259. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 70% of the pre-irradiation value.

260. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 60% of the pre-

irradiation value.

261. (New) The method according to claims 178 or 179, wherein the recovery of the desired activity of the biological material after sterilization by irradiation is at least about 50% of the pre-irradiation value.